

Attorney Docket No. U 0113 N02B

Appl. No.: 10/626,281

Art Unit: 1626

**Applicant's Request for Reconsideration After the Final Action of June 8, 2005**

**REMARKS/ARGUMENTS**

**Listing of Claims**

The foregoing Listing of Claims includes the amendments presented in Applicant's response to the first office action and is provided for convenience in this document. The foregoing Listing of Claims does not introduce any amendments.

Reconsideration and withdrawal of the rejections maintained in the subject Final Action is respectfully solicited.

**Rejection of Pending Claims 1-15 and 17-40 Under 35 USC § 112, Paragraph Two**

The Examiner rejects independent claims 1 and 33-35 as being "written in functional language and therefore broader than the enabling disclosure." Applicant respectfully traverses this rejection for four reasons:

(1) MPEP §2173.05(g) expressly states:

*"There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper."*

(2) Process language is inherently functional.

(3) The wording of the claims comes from the disclosure and is, therefore, *of the same breadth* as the disclosure.

(4) Applicant's claims do particularly point out and distinctly claim the invention in a manner readily understood by the art-skilled person in light of the description in the specification.

(1) MPEP §2173.05(g) states that functional language should be evaluated for its definiteness - not dismissed out of hand as indefinite

**2173.05(g) Functional Limitations**

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is

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nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

"A functional limitation must be evaluated and considered, just like any other limitation of the claim, *for what it fairly conveys to a person of ordinary skill in the pertinent art* in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. Whether or not the functional limitation complies with 35 U.S.C. 112, second paragraph, is a different issue from whether the limitation is properly supported under 35 U.S.C. 112, first paragraph, or is distinguished over the prior art. A few examples are set forth below to illustrate situations where the issue of whether a functional limitation complies with 35 U.S.C. 112, second paragraph, was considered."

(Underlining and italics added.)

The examiner here has failed to evaluate the allegedly functional wording of the claims for their definiteness to one skilled in the art in consideration of the disclosure of the invention.

Applicant is entitled to such evaluation in the first instance in this examination, not upon appeal or in a Request for Continuing Examination or a continuing application. Applicant is entitled to know which particular terms are not considered to be understood by the art-skilled chemist and why, including the specific deficiencies in the specification with respect to such terms.

(2) Process wording is inherently functional, yet processes are specifically provided for under 35 USC §101 as useful subject matter for patents.

**"35 U.S.C. 101 Inventions patentable.**

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

(emphasis added)

According to the examiner's rejection, no process expressed in general terms can be patentable under 35 USC § 112, paragraph two, because it contains indefinite functional language.

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The court in Federal Sign & Signal Corp. v. Bangor Punta Operations, Inc. 357 F.Supp 1222, 1222 177 USPQ 737, at 746 (S.D.N.Y. 1973) states:

It has been clear at least since the case of Cochrane v. Deener, 94 U.S. 780 (1876) that a process itself is patentable, independent of the means utilized to practice it. Defendant seems to argue in a post-trial letter dated January 8, 1973 that the absence of alternative means of performing the methods make them somehow functional and unpatentable. But the recent relevant law is to the contrary, Application of Traczy-Hornoch, 397 F.2d 856 (C.C.P.A. 1968). The policy underpinnings for this position are persuasively stated in the Traczy-Hornoch decision, 397 F.2d at 868:

"The essential difficulty is in the fact that, although at the time of the application only one apparatus may be known which is capable of carrying out the process, others may become available later. In which case of course, the inventor may be cheated of his invention. It is peculiarly our responsibility to see that the decisional law does not require this kind of inequity."

...

A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery. In the language of the patent law, it is an art. The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result. The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.

(emphasis added)

In the context of the present claims, the last italicized wording may be read "but the means of performing the acts may be of secondary consequence". In other words, the examiner's statements that "under the US patent practice patentability of a process claim is determined by 'how' the process is performed" and that "the claims must recite the reagents, the reaction times, pH and reaction conditions involved in the steps" are simply incorrect.

Thus, applicant's process steps, i.e., "providing", "purifying", "solvolyzing", "reacting", "crystallizing" and "separating", are indeed patentable steps under 35 USC §112, paragraph two,

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provided they are supported in the specification (per 35 USC §112, paragraph one) and are understood by the person skilled in the art. [See (3) and (4) below.]

**(3) The wording of applicant's claims comes from the disclosure and is, therefore, *of the same breadth as the disclosure* - i.e., it is fully supported in the specification.**

Applicant's original process claim 1 is set out in the specification under the Brief Summary of the Invention on page 3, paragraph [0011]. (The present claim 1 has been amended to state purification by crystallization.)

Applicant's original process claim 33 is indeed directed to a preferred and exemplified embodiment. The wording of this more detailed process claim is stated in the specification under the Brief Summary of the Invention on page 3, paragraph [0012]. (Only the preamble of present claim 33 has been amended from the original.)

Applicant's original process claim 34 is set out in the specification under the Brief Summary of the Invention on page 4, paragraph [0013], lines 1-9.

Applicant's original process claim 35 is set out in the specification under the Brief Summary of the Invention on page 4, paragraph [0013], lines 10-13.

The Court in In re Anderson, 471 F.2d 1237, at 1241 176 USPQ 331 (CCPA 1973), stated patentee's (applicant's) entitlement to broad claims in addition to claims to preferred embodiments, as follows:

On the first point, the tacitly assumed need for exemplification, we do [\*1241] not regard § 112, first paragraph, as requiring a specific example of everything within the scope of a broad claim. In re Gay, 50 CCPA 725, 309 F.2d 769, 135 USPQ 311 (1962). There is no question raised as to the fact that there are specific examples of what appears to be the preferred embodiment and best mode contemplated by the applicant of carrying out his claimed invention; we are here dealing only with a possible alternative

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embodiment within the scope of the claims. What the Patent Office is here apparently attempting is to limit all claims to the specific examples, notwithstanding the clear disclosure of a broader invention. This it may not do. As was stated in American Anode, Inc. v. Lee-Tex Rubber Products Corp., 136 F.2d 581, 585, 58 USPQ 7, 11 (7th Cir. 1943):

...

*"HN1" There is no doubt that a patentee's invention may be broader than [\*\*9] the particular embodiment shown in his specification. A patentee is not only entitled to narrow claims particularly directed to the preferred embodiment, but also to broad claims which define the invention without a reference to specific instrumentalities.*  
Smith v. Snow, 294 U.S. 1 [at pages 11 et seq.]

(Emphasis added)

Accordingly, applicant is clearly entitled to the subject process claims of both the original and the present scope as they are fully supported in the specification per 35 USC §112, paragraph one.

4) Applicant's claims do clearly define and distinctly claim the invention in a manner readily understood by the art-skilled person in light of the description in the specification.

The particular "functional language", i.e., "providing", "purifying" "solvolyzing", "reacting", "crystallizing" and "separating", is clearly understandable to a person of skill in the chemical arts and readily conveys the substance and scope of the claim. The examiner here has made no evaluation to refute this with respect to any of the claimed terms.

The Court in Exxon Research And Engineering Company v. United States, 265 F.3d 1371, at 1375; 2001 U.S. App. LEXIS 20590; 60 U.S.P.Q.2D (BNA) 1272, [at HN1] stated for assessing the definiteness of a claim, as follows:

Section 112 paragraph 2 of the Patent Act requires that a patent specification conclude with one or more claims "particularly pointing out and distinctly claiming subject matter which the applicant [\*\*7] regards as his invention." 35 U.S.C. § 112, P 2. We have

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stated the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2. *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, 27 U.S.P.Q.2D (BNA) 1123, 1126 (Fed. Cir. 1993).

(Underlining added.)

In the instant case, applicant submits that the claim is indeed easy for the person skilled in the chemical arts to understand because the terms "providing", "purifying", "solvolyzing", "reacting", "crystallizing" and "separating", describe basic procedures in the chemical arts. They are also described and exemplified in more than sufficient detail in the specification.

As evidence of the level of understanding by the art-skilled chemist, applicant has attached copies of definitions of the subject terms from Hawley's CONDENSED CHEMICAL DICTIONARY, 12th ed., Van Nostrand Reinhold Company, New York, 1993, namely, pages 253 ("chemical reaction"), 327 ("crystallization"), 977(purification"), 1029 ("separation"), and 1076 ("solvolysis").

Applicant therefore submits that the present claims 1 and 33-35 do indeed satisfy the requirements of 35 USC §112, paragraph two, and respectfully request withdrawal of the subject rejection under that statutory section.

Neither Ex parte Fressola nor In re Zletz is relevant to the to the indefinites of Functional Language

Applicant respectfully submits that the examiner's reliance on Ex parte Fressola, Board of Appeals and Interferences, 1993 Pat. App. LEXIS 3: 27 U.S.P.Q. 2d (BNA) 1608, is misplaced. That case involved a claim 42 which read:

"42. A system for the display of stereographic three-dimensional images of celestial objects as disclosed in the specification and drawings herein."

(Underlining added.)

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The present applicant's claims do not refer to the specification, but independently, clearly claim and distinctly point out the claimed invention in wording based on that in the specification.

Further, Fressola does not relate to the use of functional language and does not relate to a process claim.

Applicants respectfully submit further that the examiner's reliance on In re Zletz, CAFC, 893 F.2d 319; 1989 U.S. App. LEXIS 19432; 13 U.S.P.Q. 2d (BNA) 1320, is also misplaced. In that case the applicant, Dr. Zletz, lost a priority contest, but was thereafter attempting to patent the following two claims over the lost interference count.

- “13. Normally solid polypropylene having a crystalline polypropylene content.
- 14. Normally solid polypropylene”

Dr. Zletz was asserting that these claims 13 and 14 were generic to a lost count.

The claims and count in question in In re Zletz are drawn to compositions and not processes - and they do not involve functional language. There is no discussion of functional language in In re Zletz. Thus, this case does not relate to the issue in the present application.

Applicant respectfully submits further that the examiner's reference to what the MPEP says about critical elements of a process step is not relevant here, for the following reasons. First, the examiner has not provided applicant with a specific reference to the MPEP section and wording to establish its relevance. Second, the issue raised by the examiner in this rejection is the use of functional language in a claim - which is the specific topic addressed by MPEP §2173.05(g) cited by applicant herein. Third, the case law cited herein is directly pertinent to evaluation of functional language (including process language) called for in MPEP §2173.05(g).

For the above reasons, withdrawal of the rejection of claim 1-15 and 17-40 because independent claims 1 and 33-35 are considered indefinite or overly broad under 35 USC §112, paragraph two, is respectfully solicited.

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**Rejection of claim 34 as a duplicate of claim 1**

Claim 34 remains rejected (under 35 USC § 112, paragraph two) as a substantial duplicate of claim 1. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1 and 34 involve substantially different process steps due to the nature of the starting material, namely, a "protecting group-substituted tocopherol compound" in claim 1 and a "a tocopherol compound" in claim 34.

In claim 1, the "protecting group-substituted tocopherol compound" could be, for example, a mixture or composition free from the other products of the protection reaction itself, which is thus purified (further) by crystallization in step (b). In claim 34, on the other hand, "a tocopherol compound" is reacted to form a reaction mixture comprising a protecting group-substituted tocopherol compound. This reaction mixture is then "separated" in step (c) in a manner to provide purified protecting group compound. Thus, even though the final result may be substantially the same, one process can be infringed without infringing the other. Since, applicant is the first to disclose and claim both processes, he is entitled to protection for both. Withdrawal of the rejection of claim 34 as a duplicate of claim 1 is therefore respectfully solicited.

**Withdrawal of rejection of claims 38-40**

Claims 38-40 appeared to be rejected in the office action of November 1, 2004 for two reasons, namely: (1) they are duplicates of claim 36, and (2) they are drawn as product-by-process claims. The rejection of these claims as duplicates was not mentioned in the subject Final Action. Thus, it appears that the rejection has been withdrawn. Acknowledgement of the withdrawal of the rejection of these claims is requested.

In the event that the rejection is indeed maintained, applicant respectfully requests that the examiner reconsider applicant's reasons for traversal set out in the reply of May 2, 2005, and withdraw the rejection.

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**Withdrawal of rejection of claims 4, 6-8, 10, 12-15, 18-19, 21, 23-24, 26-27, 29 and 31 for indefiniteness under 35 USC §112, paragraph two.**

In the first office action ( November 1, 2004), the subject dependent claims were stated to be indefinite because the word "comprise" makes the claim indefinite and should be changed to "is" (or "is by" for claim 17).

In the reply of May 2, 2005, Applicant amended claims 4, 6, 7, 12-15, 23 and 24 to change "comprises" to "is", as suggested by the examiner. The acceptance of this amendment is not acknowledged by the examiner in the subject Final Action. Nor, is the rejection continued. Applicant respectfully requests acknowledgement of the acceptance of the amendments and withdrawal of the rejection with respect to claims 4, 6, 7, 12-15, 23 and 24.

However, in the reply of May 2, 2005 applicant traversed this rejection with respect to claims 8, 10, 18, 19, 21, 26, 27, 29 and 31. The withdrawal of this rejection in view of applicant's argument is not acknowledged by the examiner in the subject Final Action. Nor, is the rejection continued. Applicant respectfully requests acknowledgement of the withdrawal of the rejection with respect to claims 8, 10, 18, 19, 21, 26, 27, 29 and 31.

In the event that the rejection is indeed maintained, applicant respectfully requests that the examiner reconsider applicant's reasons for traversal set out in the reply of May 2, 2005, and withdraw the rejection.

There are no further rejections in the subject Final Action or in the Office Action of November 1, 2005. Applicant believes that the previous amendments to the claims, and the previous and present remarks and arguments are completely responsive under 35 CFR 1.111 and completely

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avoid and/or overcome all grounds of rejection. Applicant therefore respectfully requests that a timely Notice of Allowance be issued in this application.

The Examiner is requested to telephone the undersigned attorney if any further questions remain which can be resolved by a telephone interview.

Respectfully submitted,

**NORMAN MILSTEIN**

October 11, 2005

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